Group 12

Article :Deprescribing in Frail Older People: A Randomised Controlled Trial

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Objectives

- Title and author
- The question of the paper
- The significance of the question
- Background
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Title and author's name

RESEARCH ARTICLE

Deprescribing in Frail Older People: A Randomised Controlled Trial

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The question of the paper

The question

Is deprescribing an effective way to reduce medication use in frail older adults without negatively impacting their health?

The significance of the question

This research examines whether deprescribing, reducing or stopping unnecessary medications, is a safe and useful approach for frail older adults in residential care. The key question lies in deprescribing's potential to cut down on medication use without harming these patients' health. The study suggests that deprescribing can be a valuable tool, as it successfully lowered the number of medications taken by participants without any negative health effects.

Background

Frail Older Adults: As we age, our bodies become more susceptible to illness and medication side effects. Frail older adults are particularly vulnerable due to weakened physiological reserves.

Background

Many frail older adults take five or more medications (polypharmacy) to manage various chronic conditions. While medications are essential for health, polypharmacy can be detrimental.

Background

Medication Risks: Polypharmacy increases the risk of adverse drug reactions (ADRs), where medications interact poorly or cause unintended side effects. ADRs can significantly impact frail older adults' health and well-being.

Methods

- RCT design helps researchers establish a cause-and-effect relationship between the intervention and the observed outcomes. It minimizes bias and provides strong evidence for the effectiveness (or lack thereof) of the intervention.

Methods

- The researcher chose two groups the first one is the intervention group n=47 and the other group is the control group n=48 . Ninety-five people aged over 65 years living in four RACF in rural mid-west Western Australia

RACF:residential aged care facilities

Methods

Methods

Ninety-five people aged over 65 years living in four RACF in rural mid-west Western Australia were randomised in an open study. The intervention group (n = 47) received a deprescribing intervention, the planned cessation of non-beneficial medicines. The control group (n = 48) received usual care. Participants were monitored for twelve months from randomisation. Primary outcome was change in the mean number of unique regular medicines. All outcomes were assessed at baseline, six, and twelve months.

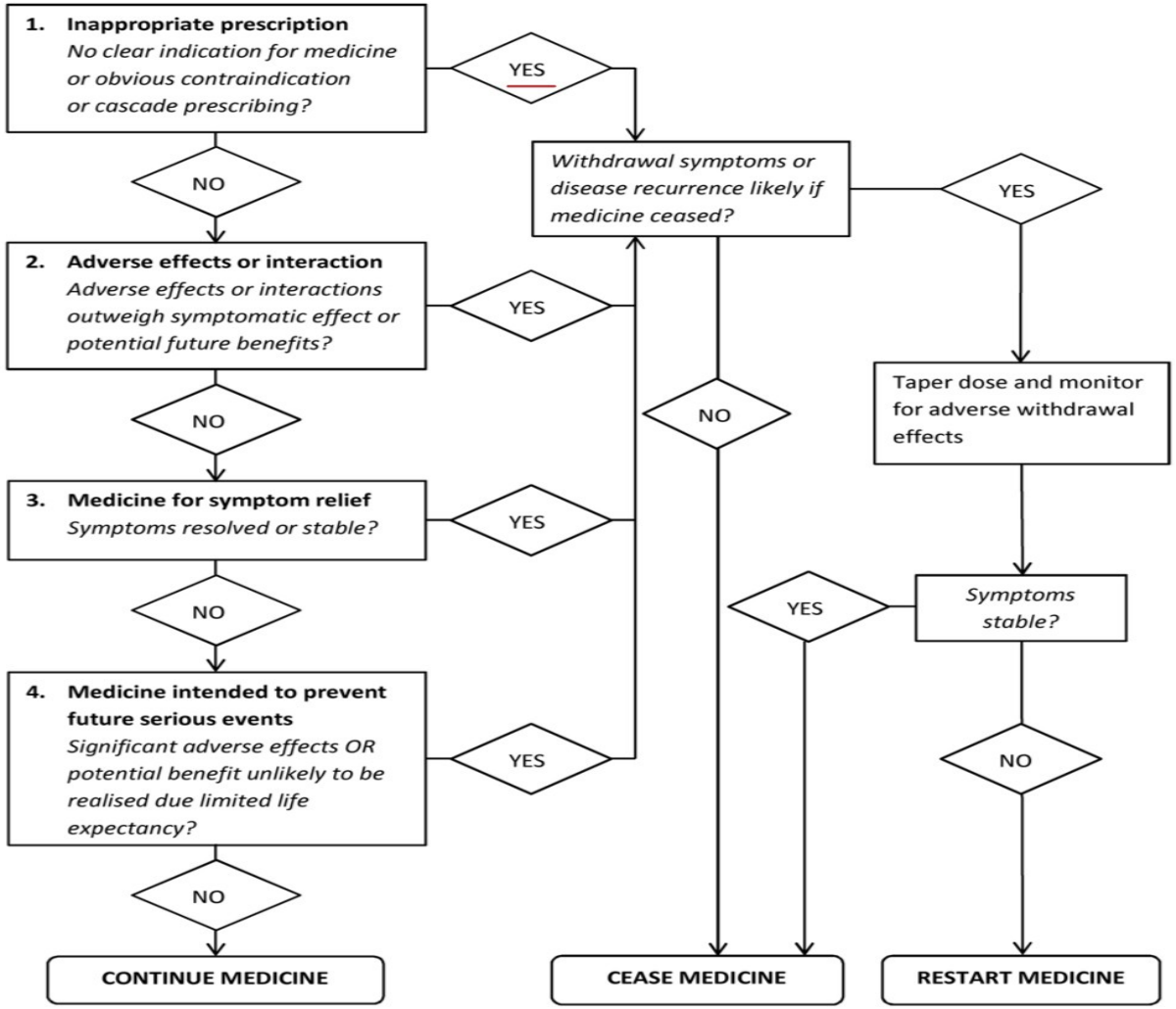
Methods

- the researchers tracked two key aspects:
  - **Medication use:** This could be quantified by the total number of medications taken by participants in each group.
  - **Health outcomes:** health outcomes were monitored, such as survival rates, falls,

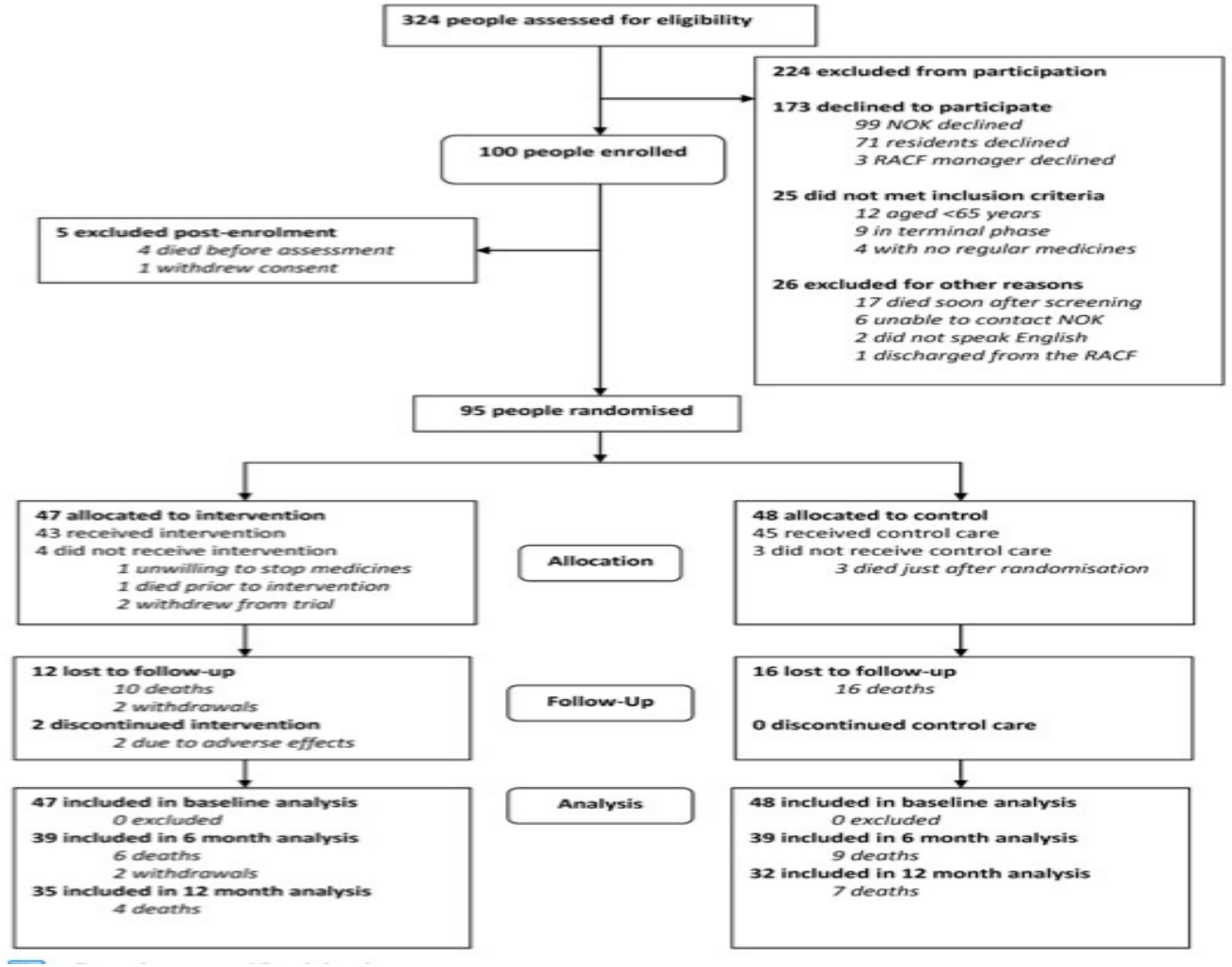
Methods

The intervention was an individualised medicine review followed by the planned cessation of non-beneficial medicines. Both groups received a medicine review but only intervention group participants were deprescribed. Both groups received regular monitoring visits from KP (a general practitioner) and usual care from their own GPs. The intention of deprescribing was to reduce the total number of unique medicines consumed by intervention group participants.

Deprescribing Algorithm.



Recruitment and Participation.



Participant recruitment

Participant recruitment

Every individual living in an RACF in Dongara or Geraldton between 19th July 2011 and 12th November 2013 was screened for eligibility (n = 324). Approximately one third of the eligible population were enrolled in the trial (n = 100, 31%). Three quarters of the participants (n = 75) had cognitive impairment (MMSE score <24) and their NOK were required to provide formal consent to participation. All participants were followed for twelve months from randomisation or until death. Two participants (1 control, 1 intervention) died less than 72 hours before their final assessment was due and one participant (control) was moribund on the due date for his final assessment. The medicines, adverse outcomes, and bowel function data from these participants were included in the 12 month analyses but other secondary outcomes were not collected. There was no difference between the groups in the frequency of review visits during the study period (intervention group 16 ± 7 review visits, control group 15 ± 6 review visits, esti-

Table 1. Baseline demographic and clinical data.

	Group	
	Intervention (n = 47)	Control (n = 48)
Gender (male, n, %)[a]	21 (45)	25 (52)
Age (years)[b]	84 (6)	84 (8)
Weight (kg)	65 (17)	69 (15)
Tibial length (cm)	37 (3)	37 (3)
BP systolic (seated or lying, mmHg)	131 (21)	123 (21)
BP systolic (standing or sitting, mmHg)	135 (22)	114 (19)
BP diastolic (seated or lying, mmHg)	69 (13)	66 (10)
BP diastolic (standing or sitting, mmHg)	75 (17)	66 (16)
Heart rate (seated or lying, bpm)	71 (13)	72 (12)
Heart rate (standing or sitting, bpm)	78 (14)	83 (16)
MMSE (/30)	15 (10)	13 (8)
MBI (/100)	48 (35)	45 (32)
QOLAD (/52, n = 30, n = 30)	33 (6)	32 (6)
EQ-5D (/100, n = 28, n = 27)	71 (15)	63 (19)
NPI-NH sleep section (/12, n = 39, n = 45)	3 (4)	1 (3)
PSQI (/21, n = 17, n = 8)	5 (3)	5 (3)
Number of bowel motions	10 (6)	11 (6)
Any episodes of faecal incontinence (n, %)	19 (40)	16 (33)
Number of episodes of faecal incontinence	9 (9)	10 (7)
Number of days bowels not open	6 (3)	5(3)
Regular medicines	9.6 (5.0)	9.5 (3.6)
PRN and nurse-initiated medicines	4.3 (3.1)	3.5 (2.2)
PRN used	1.8 (1.7)	1.2 (1.4)
PRN not used	2.5 (2.4)	2.4 (2.0)
Target medicines for deprescribing	7.4 (3.8)	7.9 (3.7)

Numbers are mean (SD) or n (%).

[a]35% of screened residents were male.

[b]Mean age of eligible non-participants was 85 ± 7 years.

Results

- The study likely reported a statistically significant **reduction in the number of medications taken** by participants in the deprescribing group compared to the control group. This indicates that the intervention successfully achieved its goal of reducing medication use in frail older

Results

Outcomes

Primary outcome. The primary outcome was the mean change in the number of unique regular medicines consumed by participants at 12 months post-randomisation. The total number of regular medicines was comprised of all regular medicines, any PRN, nurse-initiated or self-administered medicine that had been used more frequently than once per week during the preceding 3 month period (>13 doses), and any short term medicine (eg. antibiotics, topical

Secondary outcomes

- Survival at 12 months post-randomisation.
- Proportion of participants experiencing a fall or non-vertebral fracture (confirmed by radiological assessment). A fall was defined as anything reported as a fall in the progress notes or any incident where a participant was found kneeling, sitting, or lying on the floor by NOK or an RACF staff member.

Results

- These results suggest that deprescribing can be a safe and effective approach for reducing medication use in frail older adults. By successfully lowering medication burden without compromising health, deprescribing has the potential to improve the well-being of this vulnerable population

Results

- Importantly, the research should have examined if this medication reduction came with any health risks. The results likely showed **no significant differences** in health outcomes between the two groups. In simpler terms, the deprescribing intervention did not worsen factors like survival rates, falls, cognitive function, or quality of life in the participants.

Results

- Statistically significant" implies a strong likelihood that the observed decrease in medication use wasn't due to chance but resulted from the intervention.

"No significant differences" means that any changes in health outcomes between the groups were likely due to random chance and not the deprescribing intervention itself.

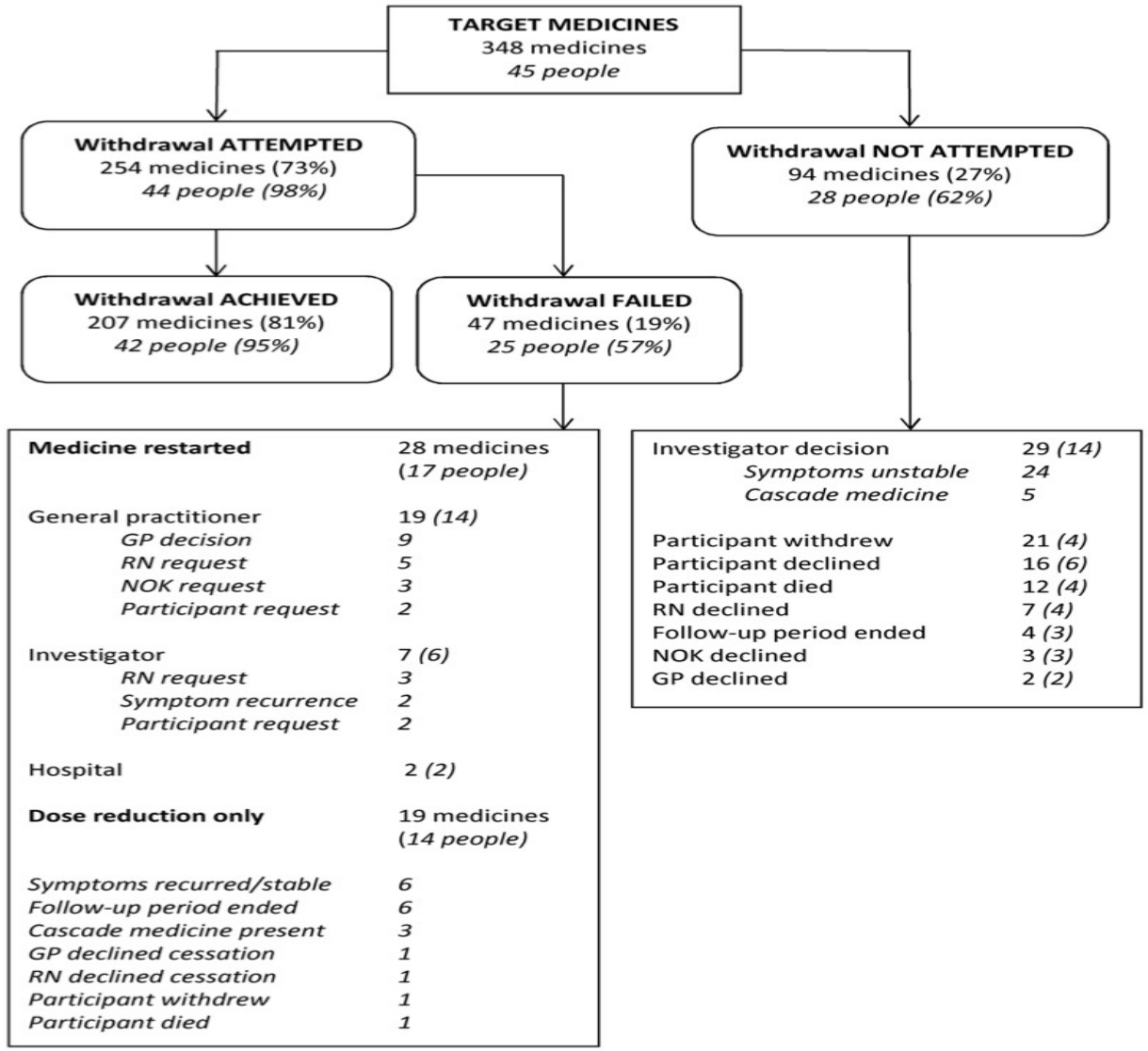


Fig 3. Deprescribing Outcomes. "Withdrawal Achieved" means medicine ceased or changed to PRN used less frequently than once per week at the last follow-up assessment point; RN, registered nurse; NOK, next of kin; GP, general practitioner. Percentages for "Withdrawal Failed" and "Withdrawal Achieved" are calculated as a percentage of the "Withdrawal Attempted" total. Italic numbers in () in the two large explanatory boxes refer to number of people.

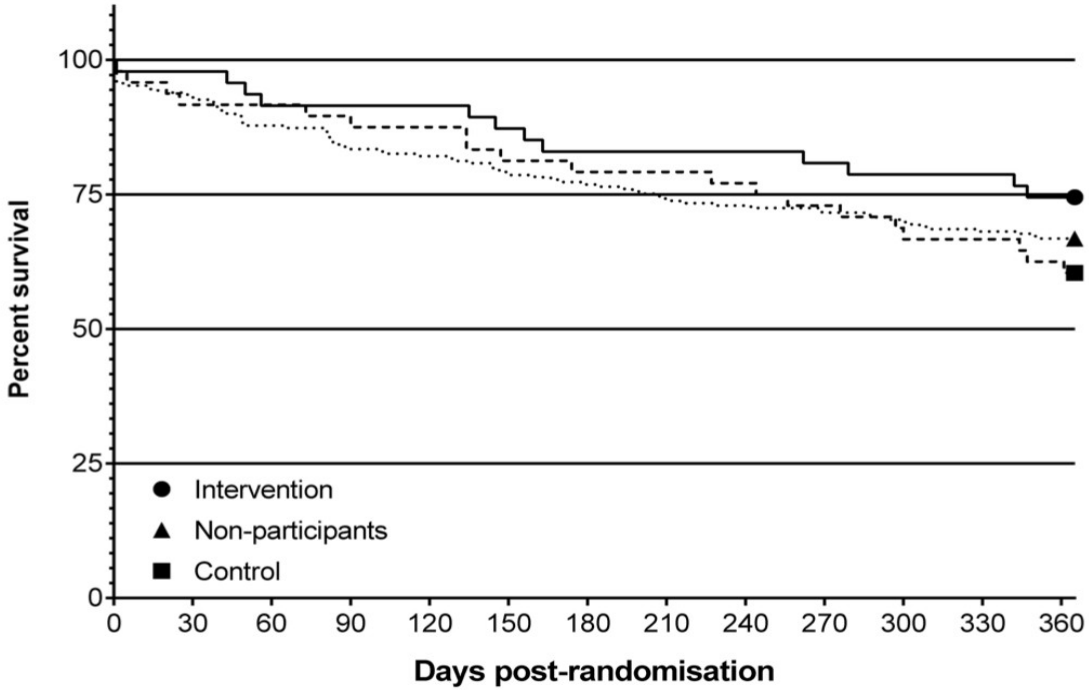


Fig 5. Kaplan Meier survival plot to 12 months post-randomisation.

Mortality

Survival data are presented in Fig 5. In the twelve months from randomisation there were deaths in the intervention group (26% mortality) and 19 deaths in the control group (40% tality, χ^2 1.9, df 1, p = 0.16, HR 0.60, 95%CI 0.30 to 1.22)

Discussion/Conclusions

As we discussed, the study's central question was whether deprescribing could safely reduce medication use in frail older adults.

Discussion

Deprescribing reduced the number of regular medicines consumed by frail older people living in residential care in rural Western Australia. Risk-modifying medicines (aspirin, statins, antihypertensives, bisphosphonates, calcium, and vitamin D) were more successfully deprescribed than symptom-modifying medicines (analgesics, laxatives, antidepressants, hypnotics, and anxiolytics). The reduction in medicines at twelve months (two medicines per person) was half the number of medicines ceased during the trial (four medicines per person) and considerably smaller than the number of medicines selected for deprescribing (seven to eight medicines per person), confirming the difficulty of reducing polypharmacy in practice.

The main weakness of this study is the small sample size. We were unable to accurately estimate the effect of deprescribing on clinical outcomes other than the number of prescribed medicines or rule out adverse effects from the intervention. In addition, there were differences between groups at baseline in blood pressure and in medical diagnoses that may have affected the secondary outcomes, including survival rates.

The open design, while representing actual clinical practice, is also a major weakness, making it difficult to eliminate treatment biases or informal deprescribing in control group participants. Our protocol allowed GPs, RNs, and/or NOK to decline the cessation of any medicine in cognitively impaired participants. Although this might have hindered effective deprescribing, our data show that fewer than 4% of planned cessations were vetoed by a GP, nurse, or family member.

More than three-quarters of our study participants had dementia. Many of these people had difficulty reporting symptoms or adverse medicine withdrawal effects. We regularly checked progress notes and asked RACF staff about specific withdrawal symptoms, but we may have

Discussion

underestimated the negative effects of deprescribing in this population. People with advanced dementia were also unable to reliably complete sleep, quality of life and self-reported general health assessments. Our data on these outcomes are incomplete and unreliable. Using a proxy to assess these outcomes would have strengthened the data.

The main strength of this study is that we actively deprescribed rather than relying on indirect deprescribing methods such as recommendations to prescribers. The RACF setting meant we had accurate records of the medicines being consumed by our participants and we were able to confirm that deprescribed medicines were actually ceased. We minimised potential sources of bias by having a blinded research nurse assess the more subjective outcomes. Additional strengths are a randomised design with prospective registration of the protocol, per-protocol statistical analyses, and an appropriate control group treated as similarly as possible to the intervention group.

Discussion/conclusion

- This study compared with previous research on deprescribing in older adults. Several studies have shown similar positive outcomes, suggesting deprescribing can be a valuable tool to manage polypharmacy and potentially improve well-being

Previous studies

A 2008 systematic review of 31 studies that withdrew a single class of medicine in older people reported that diuretics, antihypertensives, benzodiazepines, and psychotropic agents could often be withdrawn without causing harm, but that psychotropics had a high rate of post-trial re-instatement.[43] High quality deprescribing studies that cease more than one class of medicine are rarer. Garfinkel et al. conducted two non-randomised deprescribing studies in a geriatric hospital and in community-dwelling older adults and achieved significant reductions in medicine use in both cohorts and significant improvements in survival and self-assessed general health respectively.

Previous studies

Gallagher et al. and Dalleur et al. conducted randomised studies using the Screening Tool of Older People's Prescriptions (STOPP) to reduce the use of potentially inappropriate medicines (PIMs) in older hospital inpatients.[27,28,44] Gallagher et al. reported significantly reduced PIMs use in the intervention group at discharge and 6 months post-discharge, no change in the rate of hospital readmission, and non-significant reductions in falls, all cause-mortality, and GP visits during the 6 month follow-up period in 382 people aged 65 years and older.[27] Dalleur et al. enrolled frail inpatients aged over 75 years and reported reduced PIMs use in the intervention group on discharge, although the proportion of people prescribed at least one PIM was not altered.

Previous studies

Another recent randomised study investigated the effect of nurse training on potentially harmful medicine use in 227 residents of assisted living facilities in Helsinki and reported a small reduction in the use of potentially harmful medicines (-0.43, p = 0.004), fewer days in hospital, and a non-significant increase in mortality at 12 months in intervention group participants.[29]

Discussion

Our results, when combined with evidence from these earlier studies, suggest that it may be possible to deprescribe in frail older people without adversely affecting survival or outcomes related to quality of life. We found that risk-modifying medicines with no symptomatic benefit were simple to deprescribe. We considered cessation of these medicines to be appropriate in people close to death where quality of life was a higher priority than extending survival. Our follow-up period was too short and participant numbers too small to determine whether discontinuation of these medicines would ultimately increase fracture and vascular event rates, but the theoretical risk of these events should be weighed against futility of treatment in people with very limited life expectancy and the potential for improved quality of life through reduced adverse drug effects and a reduced pill burden. Decision-making about symptom-modifying medicines was more difficult, particularly in people with cognitive impairment who were unable to reliably report symptoms. We were able to cease analgesics, laxatives, anti-reflux remedies, antidepressants, hypnotics, and anxiolytics without incident in 40% to 70% of people in whom withdrawal was attempted. These results suggest that withdrawal of symptom-modifying medicine is worth attempting if symptoms are stable and people are adequately monitored during and after deprescribing.